

REMARKS/ARGUMENTS

Claims 1, 4-17 and 19-22 are pending. In the Office Action, claims 1, 5, 7-17 and 19-22 stand rejected on various grounds. The Applicant responds to each ground of rejection as subsequently recited herein. Reconsideration of this Application is respectfully requested.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. See MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03.

- A. Claims 1, 5, 7-9 and 11-22 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Douk et al., (US 6,911,036) in view of Lenz et al., (US 6,620,149)

The Applicant respectfully traverses this rejection. To warrant the §103(a) rejection of claims 1, 5, 7-9 and 11-22, Douk in view of Lenz must teach or suggest all the claim limitations of claims 1, 5, 7-9 and 11-22. The Applicant respectfully asserts that the Douk patent and the Lenz patent, alone or in combination, fail to disclose, teach, or suggest all the claim limitations of independent claims 1, 16 and 20.

Specifically, Douk in view of Lenz does not teach or suggest a core wire inserted through the hollow guidewire, the core wire including a tapered undulating section including a plurality of undulations along an axial portion of the core wire, wherein an amplitude of each consecutive undulation varies with axial distance from a proximal end of the core wire, the plurality of undulations frictionally contacting an inner surface of the hollow guidewire when disposed therein; as recited in independent claims 1 and 16.

The rejection alleges, at paragraph 6 (regarding claim 1) and paragraph 8 (regarding claim 16) of the present Office Action, that the Douk patent teaches a core wire having a tapered undulating section 160 that frictionally contacts an inner surface of a hollow guidewire and that

different amounts of friction can be achieved by selecting the amplitude or maximal transverse dimension of bends 160. The Applicant submits that these allegations are in error.

At most, the Douk patent teaches a core wire 142 having one or more bends 160 having equal amplitudes whose dimensions are selected such that the bent portion of the core wire fits within shaft 144 (see col. 5 lines 44-49 and FIG. 6). Nowhere within the Douk patent does it teach or suggest a tapered undulating section. Consequently, the Douk also does not teach “wherein an amplitude of each consecutive undulation varies with axial distance from a proximal end of the core wire” as recited in claim 1. In fact, the Douk patent clearly illustrates in FIG. 6 that the bends are of similar amplitude. The Lenz patent does not cure, at least, these defects.

Nowhere does the Lenz patent teach a core wire inserted through the hollow guidewire, the core wire including a tapered undulating section including a plurality of undulations along an axial portion of the core wire, the plurality of undulations frictionally contacting an inner surface of the hollow guidewire when disposed therein, as required by claims 1 and 16.

The Lenz patent teaches a corewire securement system having a metallic core member 120 fixed within hub 114 of catheter 110 such that hub 114 contains a zigzag anchoring structure 122 of core member 120 (see col. 5 lines 21-25 and FIG. 1). The Lenz patent further teaches that the zigzag anchor portion 122 is inserted into the hub lumen until the core member is affixed to the plastic inner wall of the hub lumen 144 to prevent movement of the core member anchor 122 (i.e. zigzag anchor portion 122) relative to hub lumen 144 (see col. 7 lines 4-23).

The rejection alleges, at paragraph 7, that Lenz discloses “the insertion of the core wire 120 into the hypotube is less friction than moving the core wire out of the hypotube.” Applicants aver that this statement mischaracterizes the teachings of Lenz. First, as described above, Lenz’ zigzag anchor portion 122 does not make frictional contact with an inner surface of a hollow guidewire (or hypotube), as required in claims 1 and 16. Rather, Lenz’ zigzag anchor portion 122 is disclosed as being embedded in the inner wall of the plastic hub having lumen 144. Second, nowhere does Lenz teach “moving the core wire out of the hypotube,” as alleged in the rejection. Instead, Lenz teaches anchoring, fixing or otherwise permanently securing zigzag anchor portion 122 within the plastic hub having lumen 144. Indeed, the zigzag shape may be “press fit into the hub lumen with sufficient force to secure the core member within the hub lumen” (see col. 7, lines 39-44). The stated benefit of Lenz’ structure is that “the core member can be secured

within the hub with reduced reliance on adhesives or molding of the core member within the hub body" (see Abstract).

Thus, at most, the Lenz patent teaches a core wire having a zigzag anchor that is disposed within a hub portion lumen, the hub portion attached to a proximal end of a catheter. The Lenz patent does not teach a plurality of undulations contacting an inner surface of a hollow guidewire when disposed therein.

Therefore, Douk in view of Lenz does not teach or suggest all of the claim limitations of claims 1 and 16 as required to establish *prima facie* obviousness.

The Applicant also respectfully asserts that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the references. The Douk patent is directed to a guidewire apparatus having a core wire that includes bends to provide sufficient friction to hold the core wire in the desired location after axial movement and placement of the core wire (see col. 5 lines 44-53). The device of the Lenz patent is directed to an apparatus having an anchoring device to anchor a core wire to prevent movement of the core wire (see col. 7 lines 20-22). As such, one of skill in the art would not be motivated to combine the teaching of the Lenz patent with those of the Douk patent, where to do so would destroy the intended purpose of the apparatus of the Douk patent.

For at least these reasons, claims 1 and 16 are patentable over Douk in view of Lenz. Claims 5, 7-9, 11-15, 17 and 19 depend from claims 1 or 16 and include all of the elements of their respective base claims. For at least this reason claims 5, 7-9, 11-15, 17 and 19 are patentable over Douk in view of Lenz.

Regarding claims 20 to 22, Douk in view of Lenz do not teach or suggest all of the claim limitations of independent claim 20 and thus do not support a rejection as being obvious under §103(a). Claim 20 includes the limitation of a core wire slidably inserted through the hollow guidewire, the core wire including frictional control means disposed within the hollow guidewire such that axial movement of the core wire within the hollow guidewire is easier in a first direction than in a second, opposite direction.

Neither the Douk patent nor the Lenz patent teach or suggest the core wire including frictional control means disposed within the hollow guidewire such that axial movement of the core wire within the hollow guidewire is easier in a first direction than in a second, opposite direction. As stated above, the Douk patent merely teaches bends having the same amplitude and

thus, does not teach the claimed core wire with frictional control means where axial movement of the core wire within the hollow guidewire is easier in a first direction than in a second, opposite direction. At most, the Douk patent teaches that axial movement would be the same or similar in both directions. The Lenz patent does not cure this defect. As stated above, the core wire of the Lenz patent is anchored to the walls of the hub lumen and, thus, does not teach the claimed core wire with frictional control means.

Additionally, claim 20 is a means-plus-function claim invoking 35 U.S.C. § 112, sixth paragraph. 35 U.S.C. § 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure described in the specification and equivalents thereof." As such, the Applicant's specification teaches a core wire having a tapered undulating section and that the tapered undulating section frictionally contacts an inner surface of a hollow guidewire. As stated above, the Douk patent, alone or in combination with the Lenz patent does not teach such a core wire.

For at least these reasons, claim 20 is patentable over the Douk patent in view of the Lenz patent. Claims 21 and 22 depend from claim 20 and are patentable for the same reasons discussed above regarding claim 20.

Considering the above arguments, the withdrawal of the rejection of claims 1, 5, 7-9 and 11-22 under §103(a) as being unpatentable over the Douk patent in view of the Lenz patent is respectfully requested.

- B. Claim 10 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Douk in view of Lenz and in further view of Dubrul (US Pub No. 2004/0236369)

The Applicant respectfully traverses this rejection. Claim 10 depends from independent claim 1 and includes all of the elements and limitations of independent claim 1 and, thus, is allowable for at least the same reasons as those stated above for claim 1. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. See, MPEP 2143. Applicant, therefore, requests the withdrawal of the rejection of dependent claim 10 under § 103(a).

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (978) 739-3075.

Respectfully submitted,

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